

REMARKS

Claims 1-11 remain in the application.

Claims 1-11 have been rejected under the judicially created doctrine of obviousness-type double patenting over claims 3-10 of U.S. Patent 5,293,772.

Claims 1-11 have been rejected under the judicially created doctrine of obviousness-type double patenting over claims 5-9 of U.S. Patent 5,205,159.

Claims 1-11 have been rejected under the judicially created doctrine of obviousness-type double patenting over claims 7-15 of U.S. Patent 4,986,964. Each of these rejections are traversed.

The undersigned notes that the references cited by the Examiner involve the same principle inventor of the present invention. The references describe a machine, and methodology for making measurements pioneered by the present inventor. However, the undersigned notes that there is no “overlap” as indicated by the Examiner. Rather, the claimed invention in the present application stem from new clinical findings (presented first in the present application), not recognized by any of the prior art, that the inventor has made using machines similar to but now more advanced than those described in the patent references.

For ease in analysis, the claims identified by the Examiner are attached to this response as attachment A. As can be noted from Attachment A, all of the claims referenced by the Examiner deal with methods of measuring clot elastic modulus and/or platelet contractile force. None of the claims in the referenced patents state how the measurements can be used clinically. Further, while the references cited by the Examiner discuss atherosclerosis and bleeding risk, there is no showing or suggestion in any of the references of a control or the utility of these measurements for a specific indication (note that claims 1 and 5 of the present application require comparison to a control value, and further, claims 2, 3, 6, and 7 set forth control values which are not stated or suggested from the references cited by the Examiner). Just because one can measure something does not imply or make obvious that the measurement has broad utility for a specific indication. The inventors are the only investigators who have reported that

platelet contractile force is elevated in coronary artery disease, diabetes, and vasculitis (*Vasc Endovascular Surg.* 2002 Nov-Dec;36(6):473-80 Enhanced platelet force development despite drug-induced inhibition of platelet aggregation in patients with thromboangiitis obliterans--two case reports; *Thromb Haemost.* 2002 Nov;88(5):739-44. Patients with coronary artery disease who present with chest pain have significantly elevated platelet contractile force and clot elastic modulus; *Cell Biochem Biophys.* 2003;39(2):89-99. Effect of non-heparin thrombin antagonists on thrombin generation, platelet function, and clot structure in whole blood; *Cell Biochem Biophys.* 2003;38(1):55-78. Development of platelet contractile force as a research and clinical measure of platelet function). All these reports were published after the date of filing of the current application. The finding that platelet contractile force is altered in disease states associated with endothelial damage is unique and without a precedent. Although platelet contractile force has not been available as an assay parameter prior to our work, clot retraction (an assay dependent upon platelet contractile force) has been around for two hundred years. If one searches clot retraction versus coronary artery disease, diabetes, atherosclerosis or vasculitis one finds no evidence that this connection has ever been made or even suggested. Therefore, the invention is not an obvious extension or application of this type of assay. Finally, with respect to claims 9-11 of the present application, none of the references describe or suggest the ability to monitor a treatment or therapy of a patient. This requires taking initial measurements, then providing the treatment or therapy, then making subsequent measurements. At no point do any of the cited references suggest such a course of action.

In view of the foregoing, it is respectfully requested that the application be reconsidered, that claims 1-11 be allowed, and that the application be passed to issue.

Should the Examiner find the application to be other than in condition for allowance, the Examiner is requested to contact the undersigned at the local telephone number listed below to discuss any other changes deemed necessary in a telephonic or personal interview.

A provisional petition is hereby made for any extension of time necessary for the continued pendency during the life of this application. Please charge any fees for such provisional petition and any deficiencies in fees and credit any overpayment of fees to Attorney's Deposit Account No. 50-2041.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Michael E. Whitham', is written over the typed name.

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